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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/689,136	10/12/00	ENGELHARDT J	875.032US1

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EXAMINER	
PRIEBE,S	
ART UNIT	PAPER NUMBER
1632	5

DATE MAILED: 10/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/689,136	ENGELHARDT ET AL.	
	Examiner	Art Unit	
	Scott Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Due to confusion in the claims the following assumptions have been made. Claim 63 should depend from claim 47, directed to Formula (III), not claim 44, directed to Formula (II). The formula recited in claim 63 cannot be accommodated by Formula (II). The formula recited in claim 63 is a subset of Formula (III), as indicated in the specification at page 7, and is not Formula (IV) as recited. The formula recited in claim 81 is Formula (IV).

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 29-36, 83 and 84, drawn to a method to identify an agent of Formula I that enhances AAV transduction, classified in class 435, subclass 5.

II. Claims 1-12, 37-46, 83 and 84, drawn to a method to identify an agent of Formula II that enhances AAV transduction, classified in class 435, subclass 5.

III. Claims 1-12, 47-78, 83 and 84, drawn to a method to identify an agent of Formula III that enhances AAV transduction, classified in class 435, subclass 5.

IV. Claims 1-12 and 79-84, drawn to a method to identify an agent that enhances AAV transduction by inhibiting ubiquitination, e.g. the agent of Formula IV, classified in class 435, subclass 5.

V. Claims 13, 15, 17-27, 29-36, 83 and 84, drawn to a method of altering: transduction of a mammalian lung cell by an AAV, or expression of a transgene

carried by an rAAV in a mammalian lung cell; by administering an agent of Formula I, classified in class 435, subclass 456.

VI. Claims 13, 15, 17-27, 37-46, 83 and 84, drawn to a method of altering: transduction of a mammalian lung cell by an AAV, or expression of a transgene carried by an rAAV in a mammalian lung cell; by administering an agent of Formula II, classified in class 435, subclass 456.

VII. Claims 13, 15, 17-27, 47-78, 83 and 84, drawn to a method of altering: transduction of a mammalian lung cell by an AAV, or expression of a transgene carried by an rAAV in a mammalian lung cell; by administering an agent of Formula III, classified in class 435, subclass 5.

VIII. Claims 13, 15, 17-27, and 79-84, drawn to a method of altering: transduction of a mammalian lung cell by an AAV, or expression of a transgene carried by an rAAV in a mammalian lung cell; by administering an agent that enhances AAV transduction by inhibiting ubiquitination, e.g. the agent of Formula IV, classified in class 435, subclass 5.

IX. Claims 14, 16-26, 28-36, 83 and 84, drawn to a method of altering: transduction of a mammalian liver cell by an AAV, or expression of a transgene carried by an rAAV in a mammalian liver cell; by administering an agent of Formula I , classified in class 435, subclass 5.

X. Claims 14, 16-26, 28, 37-46, 83 and 84, drawn to a method of altering: transduction of a mammalian liver cell by an AAV, or expression of a transgene carried by an rAAV in a mammalian liver cell; by administering an agent of Formula II , classified in class 435, subclass 5.

XI. Claims 14, 16-26, 28, 47-78, 83 and 84, drawn to a method of altering: transduction of a mammalian liver cell by an AAV, or expression of a transgene carried by an rAAV in a mammalian liver cell; by administering an agent of Formula III, classified in class 435, subclass 5.

XII. Claims 14, 16-26, 28, and 79-84, drawn to a method of altering: transduction of a mammalian liver cell by an AAV, or expression of a transgene carried by an rAAV in a mammalian liver cell; by administering an agent that enhances AAV transduction by inhibiting ubiquitination, e.g. the agent of Formula IV, classified in class 435, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 86.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons. Inventions I is directed to identifying agents

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each

application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 86.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons. Inventions I-IV directed to methods of identifying compounds, whereas Inventions V-XII are directed to methods of transduction. These two groups of methods are distinct because they are directed to different goals and involve different procedures and products. Inventions V-VIII and Inventions IX-XII are directed to transduction of lung cells and liver cells respectively. Thus, the methods are directed to different goals. Also, one use for the methods is gene therapy. Gene therapy for lung and liver would involve different transgenes, administration procedures and different diseases. Inventions I, V, and IX, Inventions II, VI, and X, Inventions III, VII, and XI, and Inventions IV, VIII, and XII are directed to the use of compounds of

Formulas (I), (II), (III), and (IV), respectively. These four different classes of compound are structurally very different, and in the cases of the compounds of Formulas (I)-(III) and of Formula (IV), have different biological targets.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed inventions I, V, and IX : the individual species embraced by Formulas (I). This application contains claims directed to the following patentably distinct species of the claimed inventions II, VI and X : the individual species embraced by Formulas (II). This application contains claims directed to the following patentably distinct species of the claimed inventions III, VII, and XI : the individual species embraced by Formulas (III). This application contains claims directed to the following patentably distinct species of the claimed inventions IV, VIII, and XII : the individual species embraced by Formulas (IV).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 29-36 are generic to inventions I, V, and IX; claims 37-46 are

generic to Inventions II, VI, and X; claims 47-78 are generic to Inventions III, VII, and XI; and claims 79-82 are generic to Inventions IV, VIII, and XII.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. The specific identity for each of the variable moieties present in the elected species should also be identified, e.g. the identity of R1, R2, A, B, etc. of the formula present in the elected species. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to on to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen M. Hauda, can be reached on (703) 305-6608.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

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